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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,757	11/12/2003	Eberhard Weihe	029310.52818US	4848

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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,757	WEIHE ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,19-21,26-28,32-36,40,43,46,47,53,57 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16, 19-21, 26-28, 32-36, 40, 43, 46, 47, 53, 57 and 64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 19-21, 26-28, 32-36, 40, 43, 46, 47, 53, 57 and 64 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 32-34 and 47, drawn to a method for investigating the activity of a test substance, comprising incubating the test substance with an active ingredient related to PIM-1 kinase or PIM-3 kinase, classified in class 435, subclass 4.

II. Claims 16, 19, 20, 27, 36[a-c, f(a-d)], 53, 57 and 64, drawn to a polynucleotide which is at least 90% homologous with SEQ ID NO: 7 or SEQ ID NO: 10; an antisense or peptidic nucleic acid capable of binding to the polynucleotide; a vector comprising the polynucleotide; a cell comprising said vector; a pharmaceutical composition comprising the abovementioned polynucleotides or cells; and a transgenic non-human mammal comprising an abovementioned polynucleotide, classified in class 536, subclass 23.1.

III. Claims 21 and 36[d], drawn to a protein encoded by a polynucleotide which is at least 90% homologous with SEQ ID NO: 7 or SEQ ID NO: 10 or a polynucleotide that hybridizes under stringent conditions with the abovementioned polynucleotide; and a pharmaceutical composition comprising the protein, classified in class 530, subclass 350, and class 800, subclass 13.

IV. Claims 26 and 36[e, f(e)], drawn to an antibody against a protein encoded by polynucleotide which is at least 90% homologous with SEQ ID NO: 7 or SEQ ID NO: 10 or a polynucleotide that hybridizes under stringent conditions with the abovementioned polynucleotide; and a pharmaceutical composition comprising the antibody, classified in class 530, subclass 387.1.

V. Claims 35 and 36[g, h], drawn to a compound identified as a pain-regulating substance; and a pharmaceutical composition comprising the compound, classified in class 530, subclass 300.

VI. Claims 40 and 43, drawn to a method of providing gene therapy to a mammal, comprising administering a polynucleotide, vector or cell, comprising a nucleic acid sequence which codes for PIM-1 kinase or PIM-3 kinase, classified in class 514, subclass 44.

VII. Claim 46, drawn to a method of diagnosing a mammal, comprising administering to the mammal a polynucleotide, protein, cell, antibody or compound related to PIM-1 kinase or PIM-3 kinase, and measuring a functional parameter, classified in class 435, subclass 4.

VIII. Claim 28, drawn to a transgenic non-human mammal, classified in class 800, subclass 13.

Claims 40, 46 and 47 depend from claim 36, which is claimed in a Markush type format. However, the members of the group are patentably distinct products, which can be grouped as follows: (1) polynucleotides and cells of 36[a-c, f(a-d)]; (2) proteins of 36[d]; (3) antibodies and

cells of 36[e, f(e)]. The products are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the methods of using the inventions of the groups are capable of supporting separate patents. Upon election of any group that contains any of the aforementioned claims, Applicant is required to elect one of the members of the group set forth in the claim as grouped above (i.e. (1) polynucleotides and cells of 36[a-c, f(a-d)]; (2) proteins of 36[d]; or (3) antibodies and cells of 36[e, f(e)]). This is not an election of species, but rather an election of a distinct invention, owing to the functional differences between the members of the Markush-like group.

Claims 1, 5, 13, 14, 15, 32, 33, 34, 36 and 43 are claimed in a Markush type format. However, the members of the groups do not possess unity of invention and instead are patentably distinct inventions recited in the alternative: (i) PIM-1 kinase, (ii) PIM-2 kinase, and (iii) PIM-3 kinase. The members of the group are different and patentably distinct from each other because each member is a different protein with distinct chemical structure and biological function due to their differential expression (e.g. specification page 44) and potential for phosphorylation of different substrates in tissues such as neurons and glia of the spinal cord and dorsal root ganglion. Therefore, there is no functional relationship between the members of the group (See MPEP § 803.02). Upon election of any group that contains any of the aforementioned PIM kinases, Applicant is required to elect one of PIM-1, PIM-2 or PIM-3. Furthermore, Applicant is required to indicate the sequence identifiers that contain the nucleic and amino acid sequences

for the elected PIM kinase. This is not an election of species, but rather an election of a distinct invention, owing to the functional differences between the members of the Markush-like group.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group II and Groups I and VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid, vector and cell of Group II can be used in a materially different process such as the manufacture and isolation of recombinant proteins. Further, the processes of Groups VI-VII can be practiced with another materially different product such as the polynucleotides recited in claims 1, 43, 46 and 47 that are not encompassed by the products of Group II.

Inventions of Group III and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group III can be used in a materially different process such as the manufacture of antibodies.

Inventions of Group IV and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group IV can be used in a materially different process such as Western blotting for the detection of protein expression in cell lysates.

Inventions of Group V and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group VI can be used in a materially different process such as affinity chromatography of proteins from cellular lysates.

The nucleic acids of Group II, polypeptides of Group III, the antibodies of Group IV, the compounds of Group V, and the transgenic animals of Group VIII are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

The inventions of Groups I, VI and VII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I, VI and VII comprise steps which are not required for or present in the methods of the other groups: incubating a test substance with an active ingredient (Group I), administering to a mammal a therapeutic amount of a polynucleotide or cell (Group VI); and measuring a change in

a functional parameter in a mammal caused by an active ingredient (Group VII). The end results of the methods are different: identifying a pain-regulating substance (Group I); treating a mammal (Group VI); and diagnosing a mammal (Group VII). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Except for the specific relationships described above, the inventions of Groups II-V and VIII and Groups I, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups II-V and VIII are not necessarily used in or made by the methods of Groups I, VI and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Searching more than one group would impose a serious search burden. Searching for any of the products will not necessarily identify the claimed methods. Further, each product requires a separate search of the patent and non-patent literature due to the different structural features of the protein, polynucleotide, antibody, etc. Further, each protein or nucleic acid sequence requires a separate search of the commercial sequence databases. The search for each method requires a separate search of the patent and non-patent literature to search the method step(s) not shared with any other group. Therefore, the searches are not coextensive, and the additional searching that is required to search more than one group would impose a serious search burden.

This application contains claims directed to the following patentably distinct species of the claimed invention: methods for detecting a pain-regulating substance, comprising the following sub-species types:

1. Type of cell (for example, one of claim 9), and

2. Step of measuring (for example, one of claim 1(b)):

a. If measuring binding is elected, then elect one method of measuring binding (e.g. one of claim 10).

b. If measuring a functional parameter is elected, then elect one functional parameter of claim 11 or one of claim 12.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC)

for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad

TERRY MCKELVEY
PRIMARY EXAMINER